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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,356	09/02/1999	DARIO NERI	515-4132	3100

23599 7590 09/14/2004
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/194,356	Applicant(s) NERI ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-47 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>October 9, 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 30-47 and 53-58 are pending.
Claims 48-52 have been cancelled.
Claim 58 has been added.
Claim 34 has been amended.
Claims 30-47 and 53-58 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

3. The Examiner acknowledges Applicants' submission of formal drawings on May 13, 2003.

Withdrawn Objection

Specification

4. The disclosure is no longer objected because there is a heading "Brief Description of the Drawings".

Claim Objections

5. Claim 43 is no longer objected to because of the following informality: it contains a grammatical error.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

6. The rejection of claims 30-37, 43-45, 47 and 53-57 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific binding members, single chain Fv molecules (CGS-1 and CGS-2), does not reasonably provide enablement for any specific binding member is withdrawn.

Claim Rejections - 35 USC § 102

7. The rejection of claims 30-37, 43, 47, 53 and 55-57 under 35 U.S.C. 102(b) as being anticipated by European Patent Number 0 344 134 (November 29, 1989/Reference AM on IDS) is withdrawn in light of Applicants' declaration submitted December 2, 2003.

Claim Rejections - 35 USC § 103

8. The rejection of claims 30-37, 43-45, 47, 53 and 55-57 under 35 U.S.C. 103(a) as being unpatentable over European Patent Number 0 344 134 (November 29, 1989/Reference AM on IDS), in view of Bird et al. (Science 242:423-242, 1988) is withdrawn.

9. The rejection of claims 30-37, 43, 47 and 53-57 under 35 U.S.C. 103(a) as being unpatentable over European Patent Number 0 344 134 (November 29, 1989/Reference

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AM on IDS), in view of Clackson et al. (Nature 352:624-628, August 15, 1991) is withdrawn.

Maintained Rejections and New Grounds of Rejection

Claim Rejections - 35 USC § 112

10. The rejection of claim 47 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants aver that “[t]he Examiner seems to be implying that proof of the asserted utilities is need for patentability of claim 47” and “...such proof is not necessary unless the PTO has provided reasons or evidence to doubt the...specification’s disclosure”. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants’ specification recites prophetic statements on the implementation of a therapeutic pharmacological agent. There continues to be insufficient evidence as to how the instant molecules can be employed as therapeutic nor a basis to predict their efficacy in any therapy. The applicant is advised to amend the claim to delete the recitation of “pharmaceutical” and specify the type of therapy designated for the use of a composition. For the reasons of record the rejection is maintained.

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11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 57 and 58 do not further limit from independent claim 30 and appear to be duplicate claims of claim 30.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 30-47 and 53-58 are rejected under 35 U.S.C. 101 because as written, do not sufficiently distinguish over antibodies as they exists naturally because claims 30-47 and 56-58 do not particularly point out any non-naturally occurring differences between the claimed antibodies and binding compositions and the structure of naturally occurring antibodies.

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck

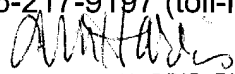
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Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the independent claims to recite "an isolated" or "purified" antibody or similar language would obviate this rejection. Likewise Applicants are advised to cancel claim 56 and implement its claim language in the independent claims.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
09 August 2004

8/9/2004